APR 3 0 2003

K031185

4 510(k) SUMMARY

1. **Submitted by:**

Abbott Laboratories, Inc.
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2. **Date Prepared:** March 5, 2003

3. **Name/Classification of Device:** Infusion Pump, Class II
80 FRN – 21 CFR Parts 880.5725

4. **Trade Name of Proposed Device:** Abbott Plum A+® Infusion Pump with HPL/RS Plug-and-Play Module

5. **Predicate Device:** Abbott Plum A+™ Infusion Pump (K011442)
Abbott Plum A+® Infusion Pump (K024084)

6. **Proposed Device Description:**

The Abbott Plum A+® Infusion Pump is an electromechanical infusion pump that uses a stepper motor in conjunction with an in-line cassette to meter IV fluids through a dedicated intravenous administration set that is also manufactured and distributed by Abbott Laboratories.

The subject and predicate devices have identical indications for use. Abbott proposes to modify the plug-and-play module of the predicate device to provide a medication error management alert feature through software changes and increasing the memory capacity of the module. The plug-and-play module will be available as a kit. In addition, there will be a separate kit that contains the software on a CD-ROM to develop the library as well as connectors to download the library from the Personal Computer (PC) to the pump. In addition, a confirmation step is being added after programming of simple delivery. These proposed changes are intended to aid in medication error reduction.

The user interface of the infusion pump allows the healthcare practitioner to program fluid delivery through a variety of weight and medication based units such as micrograms/kg/hour, grams/hr and other delivery specifications.

Like the predicate device, the display on the pump provides visible indication of several functions including active pump operations, alarm and program status and the parameters of fluid flow for one or both incoming fluid lines.

Both the predicate and the proposed devices can be used for standard, piggyback, or concurrent fluid delivery. There are no new issues of safety or effectiveness raised by the proposed Abbott Plum A+® Infusion Pump with HPL/RS Module.

7. Statement of Intended Use:

The Abbott Plum A+® Infusion Pump will be used to administer fluids into a patient's vascular system. The pump is intended for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.

This is the same intended use as the predicate device.

The pump must be used with sterile, dedicated, intravenous Plum® administration sets.

8. Summary of Technological Characteristics of New Device Compared to Predicate Device

The proposed Abbott Plum A+® Infusion Pump with HPL/RS with the plug-and-play Module and the marketed Abbott Plum A+® Infusion Pump are similar in design, materials of construction, components, intended use, labeling and manufacturing processes. Therefore, the Abbott Plum A+® Infusion Pump with HPL/RS with the plug-and-play Module and the Abbott Plum A+® Infusion Pump are substantially equivalent. The modifications do not raise new issues of safety and effectiveness

The substantial equivalence claim is supported by the information provided in the 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2003

Abbott Laboratories
C/O Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K031185
Trade/Device Name: Abbott Plum A+® Infusion Pump with a HPL/RS plug-and-play module
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: April 15, 2003
Received: April 15, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)

Device Name: **Abbott Plum A+® Infusion Pump with a HPL/RS plug-and-play module**

Indications For Use: Abbott Plum A+® Infusion Pump with a HPL/RS plug and play module has the following indications for use:

Indicated for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031185

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) **OR** **Over-The_Counter Use**_____